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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,264	06/22/2001	Sean H. Adams	11669.187USU1	8727

23552 7590 07/26/2005

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,264	ADAMS ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,28,34-38,41,43,46,52,53 and 74-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,28,34-38,41,43,46,52,53 and 74-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 5/17/05. The amendment filed 5/17/05 is acknowledged. The amendment has been entered. Claims 1, 28, 34-38, 41, 43, 46, 52, 53, and 74-78 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/06/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 28, 34-38, 41, 43, 46, 52, 53, and 74-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for screening for compounds that affect mitochondrial uncoupling wherein the method comprises contacting a mammalian cell or tissue sample with a candidate compound in vitro; analyzing expression of an 2-oxoglutarate carrier (OGC) polypeptide in the mammalian cell or tissue sample contacted with the candidate compound wherein said OGC polypeptide is at

least 95% identical to the polypeptide encoded by SEQ ID NO:1 or SEQ ID NO:2 and has mitochondrial uncoupling activity; analyzing mitochondrial membrane potential in said mammalian cell or tissue sample contacted with the candidate compound; wherein a change in the expression of the OGC polypeptide and a change in mitochondrial membrane potential relative to a control cell indicates that the candidate compound affects mitochondrial uncoupling;

does not reasonably provide enablement for the full scope encompassed by the claims for the reasons of record as set forth in the Office Action mailed on 11/17/04, reiterated below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The instant claims are drawn to methods of identifying compounds that affect uncoupling. As such, the nature of the invention is a biochemical screening assay.

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The instant claims do not explicitly indicate that the claimed method is limited to an in vitro method. Looking to the specification for guidance, it is clear that the specification contemplates that the method can be either in vitro or in vivo (e.g., see p. 19, lines 6-26). As such the claims encompass a method that can be performed on cells or tissues that are either in vitro or in vivo.

Working Examples and Guidance in the Specification

It is acknowledged that the specification contains an example wherein human OGC was overexpressed in 293 cells, resulting in the decreasing mitochondrial membrane potential (see example 1, p.48). It is noted that it appears that the 293 cells are in vitro in Example 1. Furthermore, the mitochondrial membrane potential was measured in the 293 cells that were contacted with the candidate compound. As such, the Example sets forth the basis for the notion that OGC is associates with mitochondrial membrane potential (and thus, mitochondria coupling).

Quantity of Experimentation, Unpredictability

The claims encompass a method wherein the method is performed on cells/tissues wherein the cells/tissues are in vivo (i.e., an in vivo method). Looking to the specification for guidance, there are no working examples that indicate how to perform the method in vivo. Furthermore, there is no guidance for how to analyze protein expression and mitochondrial membrane potential on living in vivo cells. The prior art does not appear to recognize any methods wherein the level of protein expression and mitochondrial membrane potential can be analyzed in living cells in vivo. The only methods found (including the present disclosure) were

for analyzing protein levels and mitochondrial membrane potential in cells in vitro. Since the claimed methods encompass methods of analyzing protein levels and mitochondrial membrane potential in living cells in vivo, and considering that methods of analyzing protein levels and mitochondrial membrane potential in living cells in vivo has not been demonstrated in the prior art, additional experimentation would be required in order for one of skill in the art to be able to use the claimed methods to their full scope. the amount of additional experimentation required to be able to make and use the methods in vivo is undue.

Level of the skill in the art

Considering that the nature of the invention, is a biochemical assay that is usually performed by individual with a high degree of educational and/or technical training in biochemistry, the level of the skill in the art is deemed to be high.

Conclusion

Considering the nature of the invention, the breadth of the claims, the limited working examples and guidance provided by the specification, and the high degree of skill required, it is concluded that the amount of additional experimentation required to perform the broadly claimed invention to its full scope is undue.

Response to Arguments

Applicant's arguments filed 5/17/2005 have been fully considered but they are not fully persuasive.

Applicants argue that they have directed the claims to a method for screening for compounds that affect mitochondrial uncoupling and the amendment renders the basis of the

rejection under 112, first paragraph moot. Applicants' also note the Examiner indicated that claim directed to methods for screening for compounds that effect mitochondrial uncoupling are enabled by the specification.

In response, it is respectfully pointed out that the Examiner indicated in the previous Office Action (11/17/2004) that "amending the claims as indicated in the enablement rejection would overcome the rejection and the claims would be allowable." The enablement rejection clearly indicated that the claims were enabled for:

A method for screening for compounds that affect mitochondrial uncoupling wherein the method comprises contacting a mammalian cell or tissue sample with a candidate compound in vitro; analyzing expression of an 2-oxoglutarate carrier (OGC) polypeptide in the mammalian cell or tissue sample contacted with the candidate compound wherein said OGC polypeptide is at least 95% identical to the polypeptide encoded by SEQ ID NO:1 or SEQ ID NO:2 and has mitochondrial uncoupling activity; analyzing mitochondrial membrane potential in said mammalian cell or tissue sample contacted with the candidate compound; wherein a change in the expression of the OGC polypeptide and a change in mitochondrial membrane potential relative to a control cell indicates that the candidate compound affects mitochondrial uncoupling.

The instant claims are not limited to the method as indicated above. For instance, although the Applicants have amended the claims to a method for screening for compounds that affect mitochondrial uncoupling, the claims are not limited to an in vitro method. As such, the claims still encompass performing the method on a living cell or tissue in vivo. Applicants have not rebutted the rejection with respect to the instant methods as they pertain to in vivo embodiments. Therefore, Applicants arguments are not persuasive to overcome the rejection. It is noted that amending the claim as indicated above (including limiting the claim to an in vitro method) would overcome the rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER